



Bristol-Myers Squibb Manufacturing Company

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VIA FEDERAL EXPRESS

July 14, 2017

Carmen Guerrero, Director
U.S. Environmental Protection Agency
Caribbean Environmental Protection Division
City View Plaza Suite 7000 #48 165 RD Km 1.2
Guaynabo, P.R. 00968-8019

**RE: Response to Comments to the Technical Review of the January 6, 2017 On-site
Surface Soil Sampling and Analysis Plan
Bristol-Myers Squibb Manufacturing Company
Humacao, Puerto Rico
EPA Facility ID Number PRD090021056**

Dear Ms. Guerrero:


Enclosed please find three hard copies including three digital copies of Bristol-Myers Squibb Manufacturing Company's (BMSMC) *Response to Comments to the Technical Review of the January 6, 2017 On-site Surface Soil Sampling and Analysis Plan*. The enclosed document has been prepared in response to the United States Environmental Protection Agency (EPA) and Puerto Rico Environmental Quality Control Board (PREQB) comments dated May 15, 2017 and received by BMSMC on May 16, 2017.

I, the undersigned, certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Response to Comments to the Technical Review of the January 6, 2017 On-site
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Bristol-Myers Squibb Manufacturing Company
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Page 2 of 2

Please feel free to call me at (787) 656-4471 or Mr. Alvin Crespo, Environmental, Health and Safety Director, at (787) 656-4364 if you have any questions.

Cordially,

A handwritten signature in blue ink, appearing to read 'Francisco Burgos', with a stylized flourish at the end.

Francisco Burgos
Environmental Affairs Manager

C: Mrs. Socorro Martínez, USEPA-CEPD
Mr. Manual O. Claudio-Rodriguez, Manager, Land Pollution Control Program, PREQB
RCRA Record Center, USEPA Region 2



Bristol-Myers Squibb Manufacturing Company

**Response to Comments to the Technical Review of the
January 6, 2017 On-site Surface Soil
Sampling and Analysis Plan**

**Bristol-Myers Squibb Manufacturing Company
Humacao, Puerto Rico**

July 14, 2017

I. GENERAL COMMENTS

1. The On-site Surface Soil SAP indicates that BMSMC is proposing developing naturally occurring and anthropogenic background threshold values (BTVs) for the Former Brule Incinerator, FTF Area, and Building 5 Area using an arithmetic mean of contaminants detected from three background surface soil samples and the arithmetic mean of contaminants detected from each area (or SWMU). However USEPA recommends a minimum of ten samples be collected and utilized for background data sets and that BTVs be statistically developed per the USEPA ProUCL Version 5.0.00 User Guide. In addition, a source-area-specific 95% upper confidence level (UCL) on the mean concentration or a point-by-point comparison should be made to determine whether contaminants exceed background. Thus, an insufficient number of background and source-area-specific surface soil samples are currently proposed by BMSMC. The On-Site Surface Soil SAP should be revised accordingly.

BMSMC Response:

BMS will revise our on-site soil sampling program and submit an amended On-Site Surface Soil SAP (SAP) to the Agency. Under our revised SAP, a minimum of ten background samples will be collected and utilized for the background data sets and BTVs will be developed as per the ProUCL Version 5.1.00 User Guide. As part of data analysis, a source-area-specific 95% upper confidence level (UCL) on the mean concentration or a point-by-point comparison will be made to determine whether contaminants exceed background. A revised SAP will be submitted to USEPA within 60 days of submittal of this Response to Comments, i.e., by September 12, 2017.

By way of update, BMSMC implemented the On-Site Surface Soil Sampling and Analysis Plan (SAP) in January 2017. The results have previously been provided to the USEPA in the April 2017 *RCRA Corrective Action Program Quarterly Progress Report No. 66 1st Quarter 2017*. In addition to addressing all USEPA comments, the revised SAP will also include a discussion of the January 2017 sampling results.

II. SPECIFIC COMMENTS

Section 2.2 Background Surface Soil Samples, Page 3; Section 2.3 Former Brule Incinerator, Page 4; Section 2.4 Former Tank Farm Area; Section 2.5 Building 5 Area Page 6; Table 2 - Specific Compounds Analyzed and Reported by Method

2. The text and tables indicate that only benzo(a)pyrene and dibenz(a,h)anthracene will be included in the target compound list for SW-846 Method 8270D - Selective Ion Monitoring (SIM). Since BMSMC proposes collecting background data set and comparing to the site-specific surface soil results, it is recommended that BMSMC include all the polycyclic aromatic hydrocarbons (PAHs) associated with this method to achieve the lowest possible reporting limits.

BMSMC Response

PAH analysis via SW-846 Method 8270 – Selective Ion Monitoring (SIM) will be incorporated in the revised SAP for all target compound list PAHs as requested by USEPA.

Also, 1,4-dioxane should be added to the target compound list for SW-846 Method 8270D-SIM. Although 1,4-dioxane was not detected above the screening levels in soils collected at the Former Brule Incinerator, FTF and Building 5 during the Phase 1 Release Assessment soil sampling, additional surface soil data confirming the absence/presence of 1,4-dioxane is recommended.

BMSMC Response

Samples will be analyzed for 1,4-Dioxane via Method 8270 (SIM) and the SAP will incorporate additional surface soil sampling for 1,4-Dioxane in potential source areas.

Section 2.2 Background Surface Soil Samples, Page 3

3. As indicated in General Comment No. 1, a minimum of ten surface soil samples should be collected to establish background surface soil concentrations (a.k.a., BTVs) per guidance provided in *USEPA ProUCL Version 5.0.00 User Guide*. Please revise the SAP accordingly.

BMSMC Response:

Please see response to General Comment 1 above.

Section 2.6 Quality Assurance/Quality Control, Page 7 and QAPP Worksheet #12:7:
Measurement Performance Criteria - Metals by Method 010, 7471B, 7470A

4. Equipment blanks should be collected at a frequency of 1 per 20 samples with a minimum of one per day. The text of the SAP and this QAPP worksheet should be updated to reflect the appropriate frequency.

BMSMC Response:

The January 2017 SAP and QAPP state that one equipment blank will be collected per day when reusable equipment is used. The revised SAP will state that equipment blanks will be collected at a frequency of 1 per twenty samples with a minimum of one per day when reusable equipment is used. The associated QAPP worksheet(s) will also be revised, as necessary.

Section 2.8 Data Analysis, Page 8

5. BMSMC proposes calculating an arithmetic mean for the BTVs and the source-area-specific concentrations to determine whether contaminant concentrations are above background values. However, this approach is not appropriate. BMSMC should calculate the BTVs in accordance with *USEPA Pro UCL Version 5. 0.00 User Guide*. In addition, BMSMC will need to compare soil sample results to the BTV. Alternatively BMSMC may calculate a 95% UCL for the mean concentration (with a minimum of 10 surface soil sample results) and compare it to the BTV.

BMSMC Response

Please see response to General Comment 1 above.

6. For compounds that are considered to be anthropogenic rather than naturally occurring, a simple comparison of the BTV to sample result or 95% UCL on mean may not be sufficient to attribute the contaminant to background. Additional lines of

evidence should be provided that demonstrates that this contaminant is not from former or current BMSMC operations at this facility.

BMSMC Response

As part of data analysis, additional lines of evidence will be provided to demonstrate that a contaminant is not from former or current BMSMC operations, if appropriate.